MAY 1 2 2004

K040383
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510(k) Summary

Name of Sponsor:	**DePuy Orthopaedics, Inc.** 700 Orthopaedic Drive Warsaw, Indiana 46581-0988 Est. Reg. No. 1818910
510(k) Contact:	**Dina L. Weissman, J.D.** Legal Consultant, Regulatory Affairs Phone: (574) 371-4905 FAX: (574) 371-4987
Trade Name:	**TriFlange II Acetabular Cup System**
Common Name:	Patient specific flanged acetabular cup system
Classification:	**Class II;** 21 CFR 888.3858 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis and Unclassified; prosthesis, hip, semi-constrained, uncemented, metal/polymer, non-porous, calicum-phosphate
Device Product Code:	Code: **87LPH** Code: **87 MEH**
Substantially Equivalent Device:	DePuy TriFlange Acetabular Cup System ..... K001277 DePuy Pinnacle® Acetabular System K001534
Device Description:	The patient specific TriFlange II Acetabular Cup System is an acetabular cup system designed and manufactured to match the individual patient's anatomy. The system consists of a porous coated acetabular cup with three patient specific illial, ischial and pubic flanges added to reinforce weak acetabula. The device may be fixed in place with titanium bone screws of various lengths through a variety of screw holes in the flanges.
Intended use:	The TriFlange II Acetabular Cup System is intended to be used with modular liners to resurface the acetabular socket in cementless application during total hip arthroplasty.
Indications for use:	The system is intended to be used with modular liners to resurface the acetabular socket in cementless application during total hip arthroplasty.

Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components.

Total hip replacement is indicated in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

Substantial equivalence:

The TriFlange Acetabular Cup System with patient specific flanges is substantially equivalent to the currently marketed TriFlange Acetabular Cup System (K001277) and the DePuy Pinnacle Acetabular Cup (K001534).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 2 2004

Ms. Dina L. Weissman, J.D.
Legal Consultant, Regulatory Affairs
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K040383
Trade/Device Name: TriFlange II Acetabular Cup System
Regulation Number: 21 CFR 888.3858
Unclassified
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Prosthesis, hip, semi-constrained, uncemented, metal/polymer, non-porous, calcium-phosphate
Regulatory Class: II
Product Code: LPH, MEH
Dated: February 16, 2004
Received: February 17, 2004

Dear Ms. Weissman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

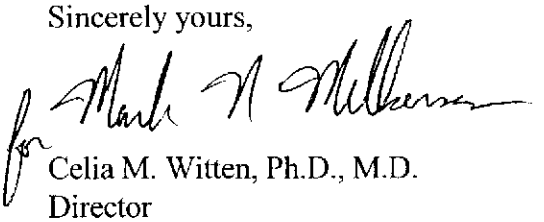
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040383

Device Name: TriFlange II Acetabular Cup System

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

(Posted November 13, 2003)

510(k) Number K040383